

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT CINCINNATI**

PRASCO, LLC,

Plaintiff,

V.

MEDICIS PHARMACEUTICAL
CORPORATION, and IMAGINATIVE
RESEARCH ASSOCIATES, INC.,

Defendants.

Civil Action No. 1:06cv00313

Judge Michael R. Barrett

FILED ELECTRONICALLY

**PRASCO'S MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT**

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Plaintiff Prasco, LLC respectfully submits this memorandum of law in opposition to Defendants Medicis Pharmaceutical Corporation's ("Medicis") and Imaginative Research Associates, Inc.'s ("Imaginative") (collectively, "Defendants") motion to dismiss Prasco's Amended Complaint for lack of subject matter jurisdiction.

INTRODUCTION

This action arises out of Prasco's marketing and sale of a generic OSCION™ Cleanser (benzoyl peroxide) 3%, 6%, and 9% in the United States, which product directly competes with Medicis's TRIAZ® Cleanser as a fully-substitutable generic equivalent. To protect its monopoly on its TRIAZ® cleanser products, Medicis marked its TRIAZ® products with U.S. Patent Nos. 5,254,334 ("the '334 patent"); 5,409,706 ("the '706 patent"); 5,632,996 ("the '996 patent"); and 5,648,389 ("the '389 patent") (collectively, "the patents-in-suit"). In doing so, Medicis affirmatively declared that a claim for infringement damages under such patents could, and likely would, be asserted by Medicis against any company that attempts to market and sell a generic version of TRIAZ® cleansers in the United States prior to the expiration of such patents.

While Medicis or Imaginative (which purports and claims to own, and/or to have the right to enforce the '334, '706 and '996 patents) has not yet sued Prasco for infringement of the patents-in-suit, the key is "yet" as either certainly can—and Prasco has a reasonable apprehension that Defendants will—bring suit in the near future. Prasco therefore filed its complaint seeking a judicial declaration that the manufacture, use, sale, offer for sale or importation of Prasco's generic OSCION™ Cleanser (benzoyl peroxide) 3%, 6%, and 9% has not infringed, and will not infringe, any valid claim of the patents-in-suit.

Defendants have moved to dismiss for failure to satisfy the “reasonable apprehension” test for subject matter jurisdiction. But based on the totality of the circumstances, Prasco certainly satisfies that test here. Indeed, there is no doubt that Prasco’s apprehension is objectively reasonable. For example, Medicis marked its products with the ‘334 patent, the ‘706 patent, the ‘996 patent and the ‘389 patent. This conduct affirmatively represents to the world that Medicis can and will sue for damages from any company that attempts to market and sell a generic version of TRIAZ[®] cleaners in the United States for patent infringement. Medicis also has an undeniable policy and history of vigorously enforcing its patents against companies, including Prasco, seeking to market competing generic products, particularly its “core products.” In fact, of particular relevance, Medicis admittedly filed suit against Prasco in just the last twelve (12) months seeking a declaration that a competing cleanser product manufactured by Prasco infringed Medicis’s patent there. (And, before doing so, Medicis made no “explicit” threat of suit—rather, Medicis hauled Prasco into court, on a preliminary injunction, at considerable expense, burden and market risk to Prasco). Indeed, with Prasco presently serving as the only competitor to Medicis for this market, Prasco harbors no doubts that Medicis can and does intend to proceed in a similar manner against Prasco here with respect to Prasco’s OSCION[™] product. And, of course, Defendants steadfastly have refused to provide Prasco a covenant not to sue or stipulation that Prasco’s generic OSCION[™] Cleanser (benzoyl peroxide) 3%, 6%, and 9% does not infringe the patents-in-suit, or otherwise to state their true intentions with regard to such patents. If Defendants believe that Prasco does not infringe, or if they really have no intention of suing, they could easily say so and resolve this case. That Defendants refuse to do so only confirms the reasonableness of Prasco’s apprehension. Thus, viewing the totality of the circumstances, as this Court must, Prasco has a reasonable apprehension of suit.

Medicis further argues that this Court must disregard the allegations of Prasco's Amended Complaint and focus only on those allegations of the original complaint. Not so. The Amended Complaint controls for purposes of determining whether a reasonable apprehension of suit exists here. But even if the Court were limited to the original complaint, such allegations more than adequately demonstrate a reasonable apprehension under the totality of the circumstances. Accordingly, Defendants' motion to dismiss must be denied.

FACTUAL BACKGROUND

This case involves Medicis' TRIAZ[®] products, including TRIAZ[®] (benzoyl peroxide) Cleanser 3%, 6%, and 9%. Medicis considers TRIAZ[®] to be among its "core brands." (Am. Compl. ¶ 10; MTD Br.¹ at 15-16). Medicis has marked its TRIAZ[®] products with the following U.S. patent numbers: 5,648,389; 5,254,334; 5,409,706; and 5,632,996. (Am. Compl. ¶ 13; MTD Br. at 16-18). The labeling and package insert for Medicis's TRIAZ[®] products expressly states: "TRIAZ[®] 3%, 6%, and 9% Cleansers *covered* by US Patents: 5,648,389; 5,254,334; 5,409,706; and 5,632,996." (Am. Compl. ¶ 14) (emphasis added). Unlike other drug products, Medicis did not file a new drug application or abbreviated new drug application with the United States Food and Drug Administration seeking the right to market its TRIAZ[®] drug product. (Am. Compl. ¶ 15).

By marking its TRIAZ[®] cleanser products with the '389, '334, '706, and '996 patents, Medicis has put all prospective companies on notice that a claim for infringement—and, more critically, patent infringement damages—of such patents could, and likely would, be asserted by Medicis against any company (like Prasco) that attempts to market and sell a generic

¹ References to "MTD Br." are to the Defendants' Brief in Support of Motion to Dismiss Amended Complaint filed on September 5, 2006.

version of TRIAZ[®] cleansers in the United States prior to the expiration of such patents. As Medicis concedes in its brief (MTD Br. at 16), the very purpose of marking the patent numbers on its products is to obtain patent damages.

**Prasco's marketing and sale of a
competing generic OSCION[™] Cleanser product**

Prasco devoted substantial resources in preparing to manufacture and sell its generic OSCION[™] Cleanser product, prior to the expiration of the patents-in-suit. (Am. Compl. ¶ 28). Prasco commercially launched its competing generic OSCION[™] Cleanser (benzoyl peroxide) 3%, 6%, and 9% in the United States in June 2006. (*Id.* ¶ 29). Despite having Prasco's product, Defendants have failed and refused to acknowledge that Prasco's generic OSCION[™] Cleanser product does not infringe the patents-in-suit, and otherwise have failed to provide Prasco any reassurance to this effect. As such, Prasco had no option but to file this suit in order to obtain patent certainty.

ARGUMENT

The essence of Defendants' argument is that no company like Prasco can ever file a viable Declaratory Judgment action unless Defendants make an *explicit* threat of suit. But such a rule would allow patentees to play coy (as Defendants have done here), while placing potential or actual competitors in a state of perpetual uncertainty when it comes to potential exposure for patent-related liability, particularly damages. The Declaratory Judgment Act was designed to avoid and prevent just these type of "scarecrow" tactics. Prasco is a small company, and as a generic company, it has thin margins. Prasco's competitive product does not infringe any of the patents-in-suit, but if this Court were to conclude otherwise, Prasco needs to know that now, rather than have a perpetual threat of infringement hanging over its head one year, three years, or even six years (the statute of limitations period for damages) from now. Similarly, Prasco needs

to protect its relationship with its customers—Prasco’s lifeblood—which would be irrevocably damaged by a patent infringement finding, particularly if such customers were subsequently pursued by Defendants for patent damages. A claim for Declaratory Judgment was designed to remove this and related commercial uncertainties.

I. Prasco Satisfies The “Reasonable Apprehension” Test For Subject Matter Jurisdiction Under The Allegations Set Forth In Its Amended Complaint.

Prasco satisfies the “reasonable apprehension” test for subject matter jurisdiction, which merely requires that (1) the patentee has created *in the declaratory plaintiff* a reasonable apprehension that the patentee will bring suit if the activity in question continues; and (2) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement. *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997). Indeed, “declaratory justiciability is needed” in these very circumstances where “(1) . . . the judgment will serve a useful purpose in clarifying and settling the legal relations in issue, and (2) . . . [the judgment] will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding.” *Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352, 1357 (Fed. Cir. 2004) (citation omitted) (vacating district court’s dismissal order declining jurisdiction over declaratory judgment action); *see also Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1346-47 (Fed. Cir. 2005) (recognizing that “uncertainty” in declaratory judgment setting could involve “uncertainty whether one will have to incur the expense and inconvenience of litigation, and how it will affect the threatened party’s customers, suppliers, and shareholders”).

Here, Prasco faces just the type of uncertainty that the Declaratory Judgment Act was designed to remedy. As such, Prasco is entitled to relief under the Declaratory Judgment Act, under which “Congress intended to prevent avoidable damages from being incurred by a person (here, Prasco) uncertain of his rights and threatened with damage by delayed

adjudication.” *Elecs. for Imaging, Inc.*, 394 F.3d at 1347 (citing *Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673 (Fed. Cir. 1991)) (internal quotation omitted).

A. Defendants do not dispute that Prasco has made, used, sold and/or offered a competitive product for sale.

Defendants do not dispute that Prasco has satisfied the second prong of the two-part test, *i.e.*, that Prasco has acted, or has made preparations to act, in a way that could constitute infringement. (*See* MTD Br. at 8 (focusing only on the “first required element”)). Nor could they. Prasco already has devoted considerable time and resources to activity that (if Prasco had an infringing product) could constitute infringement, including devoting substantial resources to the research, development and testing of its generic OSCION™ Cleanser product, all toward compiling the information necessary to market and sell its cleanser product prior to the expiration of the patents-in-suit. (Am. Compl. ¶ 28). Moreover, the parties do not dispute that Prasco currently markets its generic OSCION™ Cleanser product, which “conduct ‘qualifies as ‘present activity which could constitute infringement.’” *Cargill, Inc. v. Sears Petroleum & Transp. Corp.*, No. 02 Civ. 1396 (DC), 2002 WL 31426308, at *3 (S.D.N.Y. Oct. 28, 2002).

B. Defendants’ conduct, viewed in the totality, objectively establishes a reasonable apprehension of suit.

Defendants’ conduct otherwise, when viewed as a whole, objectively establishes that Prasco has a reasonable apprehension of suit. Significantly, Defendants do not deny that (i) Medicis marked its TRIAZ® products with the patents-in-suit; (ii) the labeling and package insert for the TRIAZ products expressly states: “TRIAZ® 3%, 6%, and 9% Cleansers covered by US Patents: 5,648,389; 5,254,334; 5,409,706; and 5,632,996”; (iii) Medicis has a history of litigious conduct in protecting its patents and drug monopolies against companies (like Prasco) intending to market competing cleanser products; and (iv) they have actively refused to give Prasco the requested assurances that Defendants will not bring suit against Prasco’s competing OSCION™

Cleanser product for such patents. Defendants' entire argument thus hinges on Defendants' assertion that they have made no *explicit* threat against Prasco to take action under the patents-in-suit. (*See, e.g.*, MTD Br. at 2 (arguing that "Prasco still does not and cannot allege that the defendants threatened it with suit"), 11). But such conduct is not necessary because "[s]uch a requirement would utterly defeat the purpose of the Declaratory Judgment Act, which in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights." *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987) (citation omitted).²

The Federal Circuit has long held that the Declaratory Judgment Act cannot be read "so narrowly as to require that a party actually be confronted with an *express* threat of litigation to meet the requirements of an actual case or controversy." *Goodyear Tire*, 824 F.2d at 956; *accord Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (recognizing that "the courts have not required an express infringement charge" (citation omitted)); *see also EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811-12 (Fed. Cir. 1996) (recognizing that "[t]he test for finding a 'controversy' for jurisdictional purposes is a pragmatic one" and that "[t]o put a putative infringer in reasonable apprehension of suit does not require an express charge of infringement and threat of suit; rather, such apprehension may be induced by subtler conduct . . ."). Rather, "[i]f the circumstances warrant, a reasonable apprehension may be found in the absence of *any* communication from defendant to plaintiff." *Arrowhead*, 846 F.2d

² Medicis further argues that it lacks enforcement rights based on a series of documents attached to various Declarations associated with its briefs. Prasco's review of such documentation shows that the party in whom enforcement rights are vested is anything but clear. Indeed, as Medicis's long-standing counsel is acting on behalf of *all* of the Defendants, it is Prasco's good faith and reasonable belief that Medicis is directing and controlling the present litigation.

at 736 (citation omitted). This is particularly true where, as in this case, a patentee has evidenced an intent to delay suit until a more convenient time. As the Federal Circuit aptly has observed:

It would obviously be unrealistic to limit the required apprehension to one of imminent suit against plaintiff when defendant is exhibiting an intent to delay that suit until after defendant's extra-judicial enforcement efforts have failed and a trial date more convenient for defendant has arrived.

Id. at 736-37 (citation omitted); *see also BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 977 (Fed. Cir. 1993) (recognizing that “[t]he purpose of the Act is to enable a person who is reasonably at legal risk because of an unresolved dispute, to obtain judicial resolution of that dispute without having to await the commencement of legal action by the other side. It accommodates that practical situation wherein the interests of one side to the dispute may be served by delay in taking legal action.”). Such apprehension may be induced by much subtler conduct that merely rises “to a level sufficient to indicate an intent [on the part of the patentee] to enforce its patent” *EMC Corp.*, 89 F.3d at 811 (citations omitted). In making this determination, the court *must consider the totality of the circumstances*, rather than focusing on isolated events or conduct. *Arrowhead*, 846 F.2d at 736; *see also C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 880 (Fed. Cir. 1983) (stating that “whether there is a federal controversy . . . can only be determined by an examination of the totality of the circumstances”).

Here, Medicis predictably ignores the totality of its conduct in favor of an improper “divide and conquer” approach, addressing each fact in isolation from the other. But viewing the *totality* of the circumstances, as this Court must, it is clear that Defendants are no mere “quiescent” patentees being dragged into court without reason.

1. Medicis's marking of its TRIAZ[®] products with the patents-in-suit gives rise to a reasonable apprehension of suit, when viewed under the totality of the circumstances.

By marking its TRIAZ[®] cleanser products with the patents-in-suit, Medicis has put all prospective companies on notice that a claim for infringement of such patents, particularly patent damages, could, and likely would, be asserted by Medicis against any company that attempts to market and sell a generic version of TRIAZ[®] cleansers in the United States prior to the expiration of such patents. There is no reason to explicitly mark a product with specific patent numbers unless the goal is to secure patent infringement damages under each such patent from a potential competitor. Medicis's patent marking thus supports, under the totality of the circumstances, a reasonable apprehension of suit.

This reasoning is entirely consistent with one of the underlying purposes of the reasonable apprehension test, which is to "protect[] quiescent patent owners against unwarranted litigation." *Arrowhead*, 846 F.2d at 736 (citation omitted). Medicis is hardly the "quiescent patent owner" who "has done nothing but obtain a patent." Medicis affirmatively marked its cleanser products, thus declaring to all prospective generic applicants, including Prasco, that an infringement suit could be reasonably asserted against them.

Medicis acknowledges that had it sent Prasco a letter listing the patents and warning that it could seek patent infringement damages against Prasco, Prasco would have a reasonable apprehension of suit. Yet that is precisely what the patent marking statute accomplishes: placing not merely the public, but all competitors on notice of a potential patent infringement claim for damages. Marking is a product-specific global warning to competitors, and is highly relevant to the totality of the circumstances analysis.

To distance themselves from their obvious reason for patent marking, Defendants try to analogize marking with patent listings in FDA's "Orange Book," suggesting that since the

latter cannot alone give rise to a reasonable apprehension of immediate suit, the former cannot either. (*See* MTD Br. at 18). They are not comparable. Marking products with patent numbers is entirely voluntary, and at the patentee's discretion. *See* 35 U.S.C. § 287(a) (stating that a patentee “*may* give notice to the public” by marking (emphasis added)), *cited in* MTD Br. at 16. FDA's “Orange Book” listings are not discretionary; they are required by statute and FDA regulation.³ Accordingly, patent marking is an entirely voluntary and affirmative representation to the world that the patentee can and will bring an infringement suit to recover damages for infringement of the marked patents in association with the marked product.

2. Medicis's litigious nature and history of asserting its patents against Prasco and others is powerful objective evidence that a reasonable apprehension of suit exists here, under the totality of the circumstances.

Medicis undeniably is a litigious company that aggressively defends its intellectual property and drug monopolies from generic competition by Prasco and others by filing litigation in connection with its products that a generic competitor may be seeking to market and sell. This is yet another factor for this Court to consider in reviewing the totality of the circumstances. *See C.R. Bard*, 716 F.2d at 881 (recognizing that “a willingness . . . to enforce . . . patent rights . . . is a factor to be considered in determining whether there is a threat of an infringement suit” (citation omitted)); *Clontech Labs., Inc. v. Life Techs., Inc.*, No. Civ.A.

³ Orange Book listings require a company submitting a new drug application (“NDA”) under 21 U.S.C. § 355(b) to also submit information (*e.g.*, the patent number and expiration date) regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1). FDA publishes patent information submitted by an NDA-holder in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”). No NDA is at issue here. (Am. Compl. ¶ 15).

AW-00-1879, 2000 WL 33124811, at *2 (D. Md. Dec. 20, 2000) (recognizing that “‘a patent owner’s willingness and capacity to enforce its patent rights is pertinent to the inquiry for an actual controversy’” (citation omitted)).

As an example, on or about October 27, 2005, with no prior advance warning (and in connection with a product that lacked patent markings), Medicis sued Prasco and another generic company in the United States District Court for the District of Arizona seeking a declaration that Prasco’s competing PRASCION™ cleanser product infringed Medicis’s patent. Medicis sought both damages as well as preliminary and permanent injunctions to prevent Prasco from continuing to market and sell a competing generic cleanser product. Even though the district court ultimately denied Medicis’s request for a preliminary injunction, Medicis stated that it would continue to “vigorously pursue” the issue “through additional legal avenues.” Indeed, Medicis has refused to terminate the litigation, instead seeking reexamination of its patent before the U.S. Patent and Trademark Office to attempt to try to use it to block Prasco from making a competitive generic product.

But Medicis’s litigious history does not stop there. Indeed, Medicis has sued numerous other companies seeking to market competing versions of Medicis’s “core products.” Medicis has filed actions against other competitors, for instance, seeking to market versions of Medicis’s PLEXION® and LOPROX® products, both of which Medicis considers (along with its TRIAZ® products) to be within its “core brands” of products.

Defendants conveniently gloss over these facts, essentially arguing that Medicis only has filed suit against Prasco one time and that Defendants have not threatened Prasco with suit here. (*See, e.g.*, MTD Br. at 2, 10). However, the mere fact that Defendants did not authorize a suit against Prasco by the time Prasco filed the present action is not dispositive of

Defendants' intentions, particularly where, as here, Medicis has engaged in a course of conduct that shows a willingness to protect its core acne cleanser franchise. *See Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 315 (S.D.N.Y. 2003). Moreover, if Defendants had no intent to claim damages or patent infringement liability in association with OSCION™, they simply could have provided Prasco with the requested covenant-not-to-sue, but have failed and refused to do so. Medicis thus has made clear that it will go to great lengths to protect its branded monopolies through litigation, including Prasco's OSCION™, which further supports a finding that a reasonable apprehension of suit exists here.

Under these circumstances, the "law does not require enterprises [such as Prasco, here] to keep their heads in the sand while a patentee [here, Medicis] picks them off one by one and at its leisure." *Arrowhead*, 846 F.2d at 738. What matters is that Medicis has engaged in conduct showing a willingness and intent to protect its core acne cleanser product monopoly from generic competition by enforcing its patents for such products against Prasco and others. *See Kos Pharms.*, 242 F. Supp. 2d at 315; *SmithKline Beecham Corp. v. Zenith Goldline Pharms., Inc.*, No. CIV.A.00-CV-1393, 2000 WL 963165, at *2 (E.D. Pa. June 28, 2000); *Goodyear*, 824 F.2d at 955-56 (finding a reasonable apprehension where, among other things, the parties were engaged in litigation concerning similar patents); *see also C.R. Bard*, 716 F.2d at 881 n.6 (recognizing that "lawsuits against other manufacturers of similar products" is a factor upon which courts have relied to find a reasonable apprehension); *Super Prods. Corp. v. D P Way Corp.*, 546 F.2d 748, 754 (7th Cir. 1977) (finding that "although the defendant had not accused the plaintiff of infringement, the plaintiff could reasonably expect infringement litigation because of the similarity of its own product to the defendant's patented product"); *Medtronic, Inc. v. Am. Optical Corp.*, 327 F. Supp. 1327, 1333 (D. Minn. 1971) (stating that "in view of the

defendant's practice of threatening suit and actually bringing suit against alleged infringers of the related '990 patent, the plaintiff could reasonably fear that the defendant would eventually sue it for infringement of the '428 patent"). Prasco thus has a reasonable apprehension that Defendants will file suit against it on the patents-in-suit. Defendants say nothing that should cause this Court to conclude otherwise.

3. Defendants have never acknowledged that Prasco does not infringe the patents-in-suit or otherwise promised not to sue Prasco.

Despite having the Prasco product, Defendants admit their *unwillingness* to provide Prasco with a covenant-not-to-sue, or to concede noninfringement (*see* MTD Br. at 18-19), but blithely presume this should not factor into the analysis. Quite the contrary, this refusal to give assurances to Prasco does matter. *See BP Chems.*, 4 F.3d at 980 (recognizing that "a patentee's refusal to give assurances that it will not enforce its patents is relevant"); *Kos Pharms.*, 242 F. Supp. 2d at 317 (same); *Gen. Latex & Chem. Corp. v. BASF Corp.*, C.A. No. 99-038-SLR, 1999 U.S. Dist. LEXIS 22904, at *8 (D. Del. July 14, 1999) (same). Indeed, it is highly relevant given one of the principal purposes of the Declaratory Judgment Act—to determine whether a party's conduct infringes when, as here, the patentees refuse to give a straight answer to the question of infringement. As Judge Learned Hand observed a half century ago in a patent case:

[I]f a manufacturer fears that he will be charged to infringe, he can always inquire of the patentee, and if the answer is unsatisfactory, he can bring an action for a declaratory judgment. ***The time has now passed when a patentee may sit by and refuse to show his hand.***

Clair v. Kastar, 148 F.2d 644, 646 (2d Cir. 1945) (emphasis added). The Supreme Court has acknowledged Judge Hand's concerns, noting that the Declaratory Judgment Act was designed in large measure to provide a remedy for parties, like Prasco here, otherwise unable to challenge

“scarecrow” patents, *i.e.*, patents on which the patentees do not bring suit but which can deter and threaten a competitor and its customers. *See Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 95-96 (1993). In fact, in *Cardinal*, the Supreme Court expressly stated that “[m]erely the desire to avoid the threat of a ‘scarecrow’ patent . . . may . . . be sufficient to establish jurisdiction under the Declaratory Judgment Act.” *Id.* at 96.

Here, Defendants have had Prasco’s product, together with more than ample time to evaluate it. Defendants could avoid litigation over the patents-in-suit simply by a formal acknowledgement that Prasco does not infringe or that Defendants will not sue. *See Supersack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995). Such an acknowledgement would moot the controversy by precluding any future assertion of those patents against Prasco. That Defendants may not be legally obliged to respond to Prasco’s demand for such an acknowledgement is beside the point. Their decision to reserve all of their rights under those patents, including their right to assert them against Prasco, buttresses and confirms Prasco’s reasonable apprehension that Defendants will attempt to enforce them.

Given the circumstances here, which this Court must analyze in their totality, Prasco has sufficiently demonstrated that Prasco has a reasonable apprehension of suit over the patents-in-suit.

II. Prasco Likewise Satisfies The Reasonable Apprehension Test Under The Allegations Set Forth In The Original Complaint.

Realizing that Prasco clearly satisfies the reasonable apprehension test, Defendants fill their brief with rhetoric about which allegations the Court should consider, all in an apparent attempt to muddy the otherwise straightforward analysis here, which leads but to one conclusion—Prasco has a reasonable apprehension of suit. While the Amended Complaint

clearly controls the Court's analysis, this same conclusion is reached regardless of which set of allegations the Court considers.

A. The Court may properly consider the allegations under the Amended Complaint.

It is well-established that “[w]hen a plaintiff files an Amended Complaint, the date of that second filing becomes the controlling date for determining subject matter jurisdiction.” *Pharmachemie B.V. v. Pharmacia S.p.A.*, 934 F. Supp. 484, 489 (D. Mass. 1996) (citations omitted); *see also Citizen Elecs. Co. v. Osran GMBH*, No. Civ.A. 05-1560(ESH), 2005 WL 3484202, at *3 (D.D.C. Dec. 20, 2005) (same); *Millipore Corp. v. Univ. Patents, Inc.*, 682 F. Supp. 227, 233 (D. Del. 1987) (recognizing that “Millipore did file an amended complaint, before any answer had been filed by UPI, and the date of the filing of this amended complaint . . . thereby becomes the controlling date for purposes of determining whether Millipore had a reasonable apprehension of suit”). Thus, this Court may—and should—consider the allegations of the Amended Complaint in analyzing whether subject matter jurisdiction exists here.

Moreover, the case law cited by Defendants is readily distinguishable from the circumstances here. For example, the court in *GAF Building Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479 (Fed. Cir. 1996) did not even apply or address the reasonable apprehension test. Rather, in determining whether subject matter jurisdiction existed, the court there focused on the complaint, which “alleged a dispute over the validity and infringement of a possible *future* patent not then in existence.” *GAF*, 90 F.3d at 482. More specifically the court held “that a threat is not sufficient to create a case or controversy *unless it is made with respect to a patent that has issued before a complaint is filed.*” *GAF*, 90 F.3d at 482 (emphasis added) (also citing *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 636 (Fed. Cir. 1991) for proposition that “the existence of issued patent claims, presently unenforceable against [the declaratory judgment

plaintiff], are a requisite to litigation of a declaratory judgment action”). Therefore, because the district court “did not know with certainty whether a patent would issue or, if so, what legal rights it would confer upon [the defendant], . . . the dispute was purely hypothetical and called for an impermissible advisory opinion,” and thus was subject to dismissal. *Id.* at 482-83 (further concluding that “disputes concerning patent validity and infringement are necessarily hypothetical before patent issuance”). No such circumstances exist here, and in fact are not even alleged. Rather, all patents-in-suit already have issued.

Moreover, *Fairplay* and *MedImmune* (see MTD Br. at 8-9) do not apply here as neither even involved the court’s consideration of amended pleadings to determine whether a reasonable apprehension of suit exists. *MedImmune* further fails to provide any support for Defendants’ argument because in that case the court addressed whether a reasonable apprehension of suit existed where a license agreement was involved. The court recognized that “once the license agreement was in place and MedImmune was in compliance with the terms of the agreement, MedImmune could not be under a reasonable apprehension that it would face an infringement suit by Centocor.” *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1379 (Fed. Cir. 2005). Moreover, the court there concluded that “MedImmune can have no reasonable apprehension of suit-indeed, it can have no apprehension of suit at all-because there is nothing for which Centocor can sue MedImmune” in light of continued payments of royalties under the license agreement. *Id.* at 1381. Again, such circumstances do not exist here.

Therefore, the allegations properly set forth in the Amended Complaint should control the Court’s analysis here.

B. The allegations under the original complaint also establish a reasonable apprehension of suit by Prasco.

Even if the Court were to only consider the original complaint (which it should not), such allegations sufficiently establish a reasonable apprehension by Prasco. As Defendants admit, Prasco essentially alleged in its prior complaint all allegations set forth in the Amended Complaint, with the exception of Defendants' failure and refusal to provide Prasco a covenant not to sue. (*See* MTD Br. at 4). For the reasons discussed above, Prasco is under a reasonable apprehension that it will face suit for infringement of one or more of the patents-in-suit by manufacturing, using, selling, offering for sale or importing its competing generic OSCION™ Cleanser (benzoyl peroxide) 3%, 6%, and 9%, which competes with Medicis's TRIAZ® Cleanser products, based upon the totality of the circumstances as set forth in the original complaint, including: (i) Medicis's patent marking (Compl. ¶¶ 17-18); (ii) aggressive conduct to date in seeking to prevent generic competition, including that by Prasco, for its core acne cleanser line of products (*id.* ¶¶ 27-28); (iii) stated willingness to aggressively enforce its patents (*id.*); and (iv) emphasis on intellectual property to protect its core business units (*id.*). As such, even under the original complaint, Prasco satisfies the reasonable apprehension test.

III. Prasco's Claim For Declaratory Relief Presents A Justiciable Case Or Controversy Under Article III Of The Constitution.

While Prasco certainly satisfies the two-prong reasonable apprehension test, it does not have to for this Court to have subject matter jurisdiction. Indeed, the Federal Circuit itself has held that "there is no specific, all-purpose test," *Arrowhead*, 846 F.2d at 735; that "[t]here is no simple rule that addresses all shades of relationships between disputants," *see BP Chems.*, 4 F.3d at 978 (citations omitted); and that the reasonable apprehension test "is not . . . a prerequisite to jurisdiction in every possible patent declaratory judgment action," *Fina Oil*, 123 F.3d at 1470; *see also C.R. Bard*, 716 F.2d at 879 ("[T]he controversy requirement in the patent

field [will] *generally mean* that the declaratory plaintiff has sufficient interest in the controversy and that there is a reasonable threat that the patentee or licensor will bring an infringement suit against the alleged infringer.” (citations omitted) (emphasis added)); *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (holding that, in a declaratory judgment action, it would be difficult, if not impossible, “to fashion a precise test for determining in every case whether there is such a controversy”). Even the majority in the *Teva* case cited by Defendants concedes that the “traditional two-part test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met.” *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1335 (Fed. Cir. 2005). Thus, an actual controversy under Article III can, and does, exist outside or regardless of any reasonable apprehension of suit.⁴

According to the Supreme Court, the *only* prerequisite to jurisdiction under the Declaratory Judgment Act is an “actual controversy” under Article III, which merely requires: (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 239-40 (1937); *Bennett v. Spear*, 520 U.S. 154, 167 (1997). The facts of this case easily satisfy Article III. Prasco is marketing a generic product, in connection with which Defendants have marked the patents-in-suit on the Medicis product, thus effectively declaring that a suit for damages could be brought. Defendants’ enforcement of those patents could prevent Prasco from selling its generic product, nullifying Prasco’s significant investments in research and development and potentially subjecting Prasco to massive infringement damages. Medicis’s litigious conduct and assertion of other patents against Prasco only amplifies these facts.

⁴ Furthermore, the propriety of the reasonable apprehension test itself is currently under review by the Supreme Court, with oral argument scheduled for October 4, 2006. *See MedImmune, Inc. v. Genentech, Inc.*, No. 05-608 (S. Ct.).

Additionally, the parties have clear and adverse legal interests regarding infringement of the patents-in-suit. Prasco has invested considerable resources launching its product—an investment that could be lost if Defendants mount a successful infringement action. Thus, Prasco suffers a real, significant, and defined harm where uncertainty exists regarding its right to compete. *See Northeastern Fla. Chapter of the Associated Gen. Contractors of Am. v. City of Jacksonville, Florida*, 508 U.S. 656, 664-68 (1993) (finding injury under Article III where plaintiff was precluded by law from competing).

Moreover, Defendants are directly responsible for Prasco's injury. Defendants obtained the patents; marked the Medicis product with them; and refused to provide Prasco with any assurance that Prasco's generic product does not infringe. Finally, resolving this conflict will not lead to an advisory opinion. A declaration of non-infringement from this Court would allow Prasco to market its product without the risk of incurring massive damages. Thus, no one legitimately can dispute that Prasco would tangibly benefit from the Court's intervention. Such intervention is, in fact, the *only* way that Prasco can market its generic product free from potential infringement liability. It is difficult to conceive of a setting in which application of the Declaratory Judgment Act would be more appropriate.

CONCLUSION

For all these reasons, Defendants' motion to dismiss should be denied.

Dated: September 29, 2006.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Amy D. Brody, an attorney, hereby certify that on this 29th day of September, 2006, a true and correct copy of the foregoing **Prasco's Memorandum of Law in Opposition to Defendants' Motion to Dismiss Amended Complaint** was filed via the Court's Electronic Case Filing system (ECF) and served in the same manner upon the following counsel for Defendants:

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